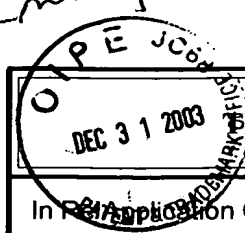


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TRANSMITTAL OF APPEAL BRIEF (Small Entity)

Docket No.
011.00250

In Re Application Of: Sol mon et al.

Serial No.	Filing Date	Examiner	Group Art Unit
09/668,119	September 22, 2000	M. Marvich	1636

Invention: **TRANSCRIPTIONAL ADAPTOR PROTEIN**

TO THE COMMISSIONER FOR PATENTS:

Transmitted herewith in triplicate is the Appeal Brief in this application, with respect to the Notice of Appeal filed on: **September 25, 3003**

Applicant is a small entity under 37 CFR 1.9 and 1.27.

A verified statement of small entity status under 37 CFR 1.27:

- ☐ is enclosed.
- ☐ has already been filed in this application.

The fee for filing this Appeal Brief is: **\$165.00**

- ☒ A check in the amount of the fee is enclosed.
- ☒ The Director has already been authorized to charge fees in this application to a Deposit Account.
- ☐ The Director is hereby authorized to charge any fees which may be required, or credit any overpayment to Deposit Account No.

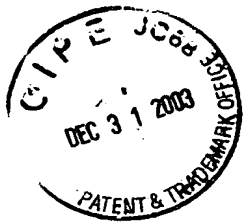
Karla M. Weyand
Signature

Dated: December 26, 2003

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<u>Karla M. Weyand</u>	
Signature of Person Mailing Correspondence	
Karla M. Weyand	
Typed or Printed Name of Person Mailing Correspondence	

CC:



011.00250

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Solomon et al.)
Serial No.: 09/668,119) Examiner: M. Marvich
Filed: September 22, 2000)
For: TRANSCRIPTIONAL ADAPTOR) Art Unit: 1636
PROTEIN)

APPEAL BRIEF

Assistant Commissioner for Patents
Washington, D.C. 20231
MS AF

Applicant hereby submits the appeal brief in triplicate
for the above-identified patent application.

I. Real Party In Interest

The real party in interest is the assignee Research
Foundation of State University of New York. The assignment was
recorded at reel/frame 011803/0891 on May 11, 2001.

II. Related Appeals And Interferences

There are currently no other appeals or interferences
known to appellant, the applicant's undersigned attorney or
assignee which will directly affect or be directly affected by
the decision in the pending appeal.

III. Status Of Claims

Claims 1-7, 13-17 and 23 are pending. Claims 8-12 and
24 are canceled. Claims 18-22 and 25-36 are withdrawn pending
allowance of claims, at which time a request will be made to
rejoin the claims. Claims 1-7, 13-17 and 23 stand rejected under
35 U.S.C. § 101 for lack of utility.

01/02/2004 HUUONG1 00000058 09668119

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IV. Status Of Amendments

An Amendment under 37 CFR § 1.116 was filed with a Certificate of Transmission by Facsimile dated September 25, 2003. The Amendment was not entered. A Supplemental Amendment under 37 CFR § 1.116 was filed concurrently with this Appeal Brief. A copy of the Amendment is attached hereto. The Advisory Action dated November 4, 2003 indicates that the Amendment was not entered because the text of the withdrawn claims was included and, therefore, the Amendment did not meet the proper revised amendment format. However, 37 CFR 1.121 states that the amendment should include the text of all pending and withdrawn claims. Accordingly, in order to comply with the Examiner's request and with the current proper amendment format, a copy of the amendment attached hereto includes the text of the withdrawn claims. An appendix is attached to the Amendment in which the text of the withdrawn claims is not included.

V. Summary of the Invention

The present invention relates to an isolated nucleic acid molecule which encodes an amino acid sequence as shown in SEQ ID NO:3 (Specification, page 15, lines 14-28). The present invention further relates to an isolated nucleic acid molecule encoding a transcriptional activator protein where said nucleic acid molecule encodes a first amino acid sequence having 90% amino acid identity to a second amino acid sequence, where the second amino acid sequence is shown in SEQ ID NO:3 (Specification, page 22, lines 12-24).

VI. Issues

(1) Whether claims 1-7, 13-17 and 23 stand rejected under 35 U.S.C. § 101 for lack of utility where the specification as filed asserts a specific, substantial and credible utility.

VII. Grouping of Claims

Claims 1-7, 13-17 and 23 stand or fall together.

VIII. Argument

A. Issue 1: Whether claims 1-7, 13-17 and 23 stand rejected under 35 U.S.C. § 101 for lack of utility where the specification as filed asserts a specific, substantial and credible utility

The claims of the above-identified patent application have a specific, substantial and credible asserted utility. As described in the specification as filed the proteins of the present invention have transcriptional regulatory activity (pg. 29, lines 25-30, pg. 15, lines 17-18, pg. 41, line 29-pg. 43, line 32.) . It is the position of the U.S. Patent and Trademark Office ("PTO") that the application has only provided guesses as to the utility. Applicant's respectfully disagree. As explicitly stated on page 15, lines 17-18, "[t]he proteins have transcriptional activation activity".

Accordingly, the specification identifies an asserted utility. Therefore, the PTO must determine if the asserted utility is specific, substantial and credible. (Manual of Patent Examining Procedure ("MPEP") 2107(B)). Only one credible asserted utility is needed to meet the criteria for 35 USC § 101 (MPEP 2107(B)(1)(ii)). Further, an applicant's asserted utility creates a presumption of utility that is sufficient to satisfy the utility requirement of 35 USC § 101 (MPEP 2107.02 III). If the asserted utility is credible, a rejection based of lack of utility is not appropriate (*Id.*). In fact, "Office personnel should not begin an evaluation of utility by assuming that an asserted utility is likely to be false, based on the technical field of the invention or for other general reasons." (MPEP 2107.02 III.A.)

In particular, the application as filed describes the transcriptional regulatory activity of the protein (pg. 29, lines 25-30, pg. 15, lines 17-18, pg. 41, line 29-pg. 43, line 32.)

In addition, the structure of the protein of the present invention is similar to a co-activator complex that mediates chromatin-directed transcriptional activation (pg. 44, lines 3-13). It is the PTO's position (as stated in the Office

Action dated May 20, 2003) that structural similarity to a known protein does not suggest functional similarity. Applicants disagree. As stated in MPEP 2107.03 II, evidence of structural similarity can be considered in an evaluation of utility. "Such evidence should be given appropriate weight in determining whether one skilled in the art would find the asserted utility credible." (Id.)

Accordingly, because there is no reason to doubt the assertion that the proteins of the present invention have transcriptional regulatory activity and that such proteins have a well-established utility, applicants asserted utility for the present case is sufficient to meet the utility requirement of 35 USC § 101. No further experimentation is necessary to attribute a utility to the claimed proteins. See *Brenner v. Manson*, 383 US 519, 148 USPQ 689 (1966).

With respect to the statement in the Advisory Action dated November 4, 2003 that applicants have not provided a substantial and specific utility, applicants respectfully disagree. As stated above, as explicitly stated on page 15, lines 17-18, of the application as filed, "[t]he proteins have transcriptional activation activity". This asserted utility is specific in identifying a use specific to the subject matter claimed (MPEP 2107.01). Further, a substantial utility (i.e. a "real world" use) is identified. (Id.). Any reasonable use that is identified for the invention that can be viewed as providing a public benefit should be accepted as a sufficient substantial utility (Id.) In particular, applicants have identified a use for the protein as those which activate transcription. As shown in the present specification, page 41, line 29 - page 44, line 2, cotransfection assays suggest that the TIG-1 protein functions as a transcriptional activating factor. In particular, TPA induced K562 cells cotransfected with the CAT reporter construct and the GAL4-TIG-1 expression vector increased cat gene expression by 11-14 fold.

Accordingly, the rejection of claims 1-7, 13-17 and 23 for lack of utility is improper and should be withdrawn.

In view of the foregoing, Applicants submit that this case is in condition for allowance and such allowance is earnestly solicited.

Respectfully submitted,

December 26, 2003

Date

Karla M. Weyand

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Signature of Person Mailing Correspondence

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IX. Appendix

1. (Previously amended) An isolated nucleic acid molecule wherein said nucleic acid molecule encodes an amino acid sequence as shown in SEQ ID NO:3.

2. (Previously amended) The isolated nucleic acid molecule of claim 1 wherein said nucleic acid molecule has a nucleotide sequence as shown in SEQ ID NO:1.

3. (Original) The isolated nucleic acid molecule of claim 1 wherein said nucleic acid is deoxyribonucleic acid.

4. (Original) The isolated nucleic acid molecule of claim 3 wherein said deoxyribonucleic acid is cDNA.

5. (Original) The isolated nucleic acid molecule of claim 1 wherein said nucleic acid is ribonucleic acid.

6. (Original) The isolated nucleic acid molecule of claim 5 wherein said ribonucleic acid is mRNA.

7. (Original) The isolated nucleic acid molecule of claim 1 wherein said nucleic acid encodes a transcriptional activity. The expression vector is selected from the group consisting of a plasmid and a virus.

8-12 (Canceled)

13. (Original) A method of decreasing expression of a transcriptional activator protein in a host cell, said method comprising introducing the oligonucleotide of claim 8 into the cell, wherein said oligonucleotide blocks translation of said mRNA so as to decrease expression of said transcriptional activator protein in said host cell.

14. (Original) A cell comprising the nucleic acid molecule

of claim 1.

15. (Original) An expression vector comprising the nucleic acid molecule of claim 1.

16. (Original) The expression vector of claim 15 wherein said expression vector is selected from the group consisting of a plasmid and a virus.

17. (Original) A cell comprising the expression vector of claim 15.

18. (Withdrawn) A method of increasing expression of transcriptional activator protein in a host cell, said method comprising:

introducing the nucleic acid molecule of claim 1 into the cell; and

allowing said cell to express said nucleic acid molecule resulting in the production of transcriptional activator protein in said cell.

19. (Withdrawn) A method of screening a substance for the ability of the substance to modify transcriptional activator protein function, said method comprising:

introducing the nucleic acid molecule of claim 1 into a host cell;

expressing said transcriptional activator protein encoded by said nucleic acid molecule in the host cell;

exposing the cell to a substance; and

evaluating the exposed cell to determine if the substance modifies the function of the transcriptional activator protein.

20. (Withdrawn) The method of claim 19 wherein said evaluation comprises monitoring the expression of transcriptional activator protein.

21. (Withdrawn) A method of obtaining DNA encoding a

transcriptional activator protein, said method comprising:

- selecting a DNA molecule encoding a transcriptional activator protein, said DNA molecule having a nucleotide sequence as shown in SEQ ID NO:1;

- designing an oligonucleotide probe for a transcriptional activator protein based on the nucleotide sequence of the selected DNA molecule;

- probing a genomic or cDNA library of an organism with the oligonucleotide probe; and

- obtaining clones from said library that are recognized by said oligonucleotide probe, so as to obtain DNA encoding a transcriptional activator protein.

22. (Withdrawn) A method of obtaining DNA encoding a transcriptional activator protein, said method comprising:

- selecting a DNA molecule encoding a transcriptional activator protein, said DNA molecule having a nucleotide sequence as shown in SEQ ID NO:1;

- designing degenerate oligonucleotide primers based on the nucleotide sequence of the selected DNA molecule; and

- utilizing said oligonucleotide primers in a polymerase chain reaction on a DNA sample to identify homologous DNA encoding a transcriptional activator protein in said sample.

23. (Original) An isolated nucleic acid molecule encoding a transcriptional activator protein, said nucleic acid molecule encoding a first amino acid sequence having at least 90% amino acid identity to a second amino acid sequence, said second amino acid sequence as shown in SEQ ID NO:3.

24. (Canceled)

25. (Withdrawn) A method of detecting presence of a transcriptional activator protein in a sample, said method comprising:

- contacting a sample with the DNA oligomer of claim 24, wherein said DNA oligomer hybridizes to any of said

transcriptional activator protein present in said sample, forming a complex therewith; and

detecting said complex, thereby detecting presence of a transcriptional activator protein in said sample.

26. (Withdrawn) The method of claim 25 wherein said DNA oligomer is labeled with a detectable marker.

27. (Withdrawn) An isolated protein, wherein said protein is encoded by a nucleotide sequence as shown in SEQ ID NO:1.

28. (Withdrawn) The protein of claim 27 wherein said protein has transcriptional activator activity.

29. (Withdrawn) The protein of claim 27 wherein said protein is encoded by an amino acid sequence as shown in SEQ ID NO:3.

30. (Withdrawn) An isolated protein encoded by a first amino acid sequence having at least 90% amino acid identity to a second amino acid sequence, said second amino acid sequence as shown in SEQ ID NO:3.

31. (Withdrawn) An antibody or fragment thereof specific for the protein of claim 30.

32. (Withdrawn) The antibody of claim 31 wherein said antibody comprises a monoclonal antibody.

33. (Withdrawn) The antibody of claim 31 wherein said antibody comprises a polyclonal antibody.

34. (Withdrawn) A method of detecting presence of a transcriptional activator protein in a sample, said method

comprising:

contacting a sample with the antibody or fragment thereof of claim 31, wherein said antibody or fragment thereof binds to any of said transcriptional activator protein present in said sample, forming a complex therewith; and

detecting said complex, thereby detecting presence of a transcriptional activator protein in said sample.

35. (Withdrawn) The method of claim 34 wherein said antibody or fragment thereof is labeled with a detectable marker.

36. (Withdrawn) A method of producing an antibody specific for a transcriptional activator protein in a host, the method comprising:

selecting the isolated transcriptional activator protein of claim 27 or an antigenic portion thereof; and

introducing the selected transcriptional activator protein or antigenic portion thereof into a host to induce production of an antibody specific for transcriptional activator protein in the host.



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Solomon et al.)
Serial No.: 09/668,119) Examiner: M. Marvich
Filed: September 22, 2000)
For: TRANSCRIPTIONAL ADAPTOR) Art Unit: 1636
PROTEIN)

APPEAL BRIEF

Assistant Commissioner for Patents
Washington, D.C. 20231
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Respectfully submitted,

December 26, 2003

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Karla M. Weyand

Signature of Person Mailing Correspondence

Karla M. Weyand

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IX. Appendix

1. (Previously amended) An isolated nucleic acid molecule wherein said nucleic acid molecule encodes an amino acid sequence as shown in SEQ ID NO:3.

2. (Previously amended) The isolated nucleic acid molecule of claim 1 wherein said nucleic acid molecule has a nucleotide sequence as shown in SEQ ID NO:1.

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4. (Original) The isolated nucleic acid molecule of claim 3 wherein said deoxyribonucleic acid is cDNA.

5. (Original) The isolated nucleic acid molecule of claim 1 wherein said nucleic acid is ribonucleic acid.

6. (Original) The isolated nucleic acid molecule of claim 5 wherein said ribonucleic acid is mRNA.

7. (Original) The isolated nucleic acid molecule of claim 1 wherein said nucleic acid encodes a transcriptional activity. The expression vector is selected from the group consisting of a plasmid and a virus.

8-12 (Canceled)

13. (Original) A method of decreasing expression of a transcriptional activator protein in a host cell, said method comprising introducing the oligonucleotide of claim 8 into the cell, wherein said oligonucleotide blocks translation of said mRNA so as to decrease expression of said transcriptional activator protein in said host cell.

14. (Original) A cell comprising the nucleic acid molecule

of claim 1.

15. (Original) An expression vector comprising the nucleic acid molecule of claim 1.

16. (Original) The expression vector of claim 15 wherein said expression vector is selected from the group consisting of a plasmid and a virus.

17. (Original) A cell comprising the expression vector of claim 15.

18. (Withdrawn) A method of increasing expression of transcriptional activator protein in a host cell, said method comprising:

introducing the nucleic acid molecule of claim 1 into the cell; and

allowing said cell to express said nucleic acid molecule resulting in the production of transcriptional activator protein in said cell.

19. (Withdrawn) A method of screening a substance for the ability of the substance to modify transcriptional activator protein function, said method comprising:

introducing the nucleic acid molecule of claim 1 into a host cell;

expressing said transcriptional activator protein encoded by said nucleic acid molecule in the host cell;

exposing the cell to a substance; and

evaluating the exposed cell to determine if the substance modifies the function of the transcriptional activator protein.

20. (Withdrawn) The method of claim 19 wherein said evaluation comprises monitoring the expression of transcriptional activator protein.

21. (Withdrawn) A method of obtaining DNA encoding a

transcriptional activator protein, said method comprising:

selecting a DNA molecule encoding a transcriptional activator protein, said DNA molecule having a nucleotide sequence as shown in SEQ ID NO:1;

designing an oligonucleotide probe for a transcriptional activator protein based on the nucleotide sequence of the selected DNA molecule;

probing a genomic or cDNA library of an organism with the oligonucleotide probe; and

obtaining clones from said library that are recognized by said oligonucleotide probe, so as to obtain DNA encoding a transcriptional activator protein.

22. (Withdrawn) A method of obtaining DNA encoding a transcriptional activator protein, said method comprising:

selecting a DNA molecule encoding a transcriptional activator protein, said DNA molecule having a nucleotide sequence as shown in SEQ ID NO:1;

designing degenerate oligonucleotide primers based on the nucleotide sequence of the selected DNA molecule; and

utilizing said oligonucleotide primers in a polymerase chain reaction on a DNA sample to identify homologous DNA encoding a transcriptional activator protein in said sample.

23. (Original) An isolated nucleic acid molecule encoding a transcriptional activator protein, said nucleic acid molecule encoding a first amino acid sequence having at least 90% amino acid identity to a second amino acid sequence, said second amino acid sequence as shown in SEQ ID NO:3.

24. (Canceled)

25. (Withdrawn) A method of detecting presence of a transcriptional activator protein in a sample, said method comprising:

contacting a sample with the DNA oligomer of claim 24, wherein said DNA oligomer hybridizes to any of said

transcriptional activator protein present in said sample, forming a complex therewith; and

detecting said complex, thereby detecting presence of a transcriptional activator protein in said sample.

26. (Withdrawn) The method of claim 25 wherein said DNA oligomer is labeled with a detectable marker.

27. (Withdrawn) An isolated protein, wherein said protein is encoded by a nucleotide sequence as shown in SEQ ID NO:1.

28. (Withdrawn) The protein of claim 27 wherein said protein has transcriptional activator activity.

29. (Withdrawn) The protein of claim 27 wherein said protein is encoded by an amino acid sequence as shown in SEQ ID NO:3.

30. (Withdrawn) An isolated protein encoded by a first amino acid sequence having at least 90% amino acid identity to a second amino acid sequence, said second amino acid sequence as shown in SEQ ID NO:3.

31. (Withdrawn) An antibody or fragment thereof specific for the protein of claim 30.

32. (Withdrawn) The antibody of claim 31 wherein said antibody comprises a monoclonal antibody.

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detecting said complex, thereby detecting presence of a transcriptional activator protein in said sample.

35. (Withdrawn) The method of claim 34 wherein said antibody or fragment thereof is labeled with a detectable marker.

36. (Withdrawn) A method of producing an antibody specific for a transcriptional activator protein in a host, the method comprising:

selecting the isolated transcriptional activator protein of claim 27 or an antigenic portion thereof; and

introducing the selected transcriptional activator protein or antigenic portion thereof into a host to induce production of an antibody specific for transcriptional activator protein in the host.